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Docket No.: 1059-009

IN THE UNITED STATES PATENT AND TRADEMARK  
PATENT OPERATION

In re Application of:

Barry Libin

Serial No.: 08/798,604

Filed: February 10, 1997

For: ANTIPLAQUE MOUTH RINSE

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Group Art Unit:

Examiner: Rose, S.K.

#26  
R. Harmon  
1/30/04

Assistant Commissioner for  
Patents  
Washington, DC 20231

**DECLARATION UNDER 37 CFR§1.132**

1. I, Stephen Spainhour, do hereby declare that I am employed by Ciba Specialty Chemicals, High Point, North Carolina as a microbiologist.

2. I have conducted a minimum inhibitory concentration test on mouthwash formulations which contain Triclosan and cetylpyridium chloride (CPC) alone and in combination. The purpose of testing the active ingredients individually in the same base formulation and in combination was to determine if the combination of the Triclosan and the CPC was synergistic. The tests were carried out with *Pseudomonas aeruginosa* and *Candida albicans*. The test results for *Candida albicans* are summarized in Table 1. The test against *Pseudomonas aeruginosa* failed to show any activity for any of the tested compositions.

The in vitro, minimum inhibitory concentration (MIC) in agar using *Candida albicans* (ATCC 10231) cultured on yeast malt agar for five days at 30 °C.

**Test Formulation:**

1. 90859 Placebo
2. 98059/4 0.1% Triclosan

3. 98059/5 0.1% Triclosan + 0.024 CPC

4. 98059/6 (0.024% CPC)

Results:

| Formulation | Formulation Concentration in Agar |     |    |      |      |
|-------------|-----------------------------------|-----|----|------|------|
|             | 20%                               | 10% | 1% | 0.5% | 0.1% |
| 98059       |                                   |     |    |      |      |
| 98059/4     | +                                 | +   | +  | +    | +    |
| 98059/5     | 1.                                | 2.  | +  | +    | +    |
| 98059/6     | +                                 | +   | +  | +    | +    |

+: growth

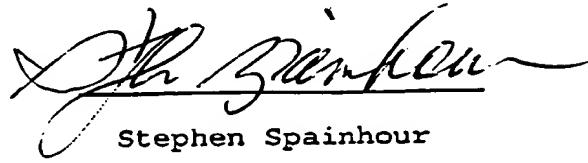
1. No growth after two days incubation. light growth  
after five days incubation.

2. Very light growth (several colonies) after two days  
incubation. Growth after five days incubation.

3. The test data show that when the Triclosan and CPC were combined and applied at a 20% concentration of the solution of Triclosan 0.1%w/w and CPC 0.24%w/w in agar, there was no growth. In cases where each of Triclosan and CPC were used alone, there was growth. These results show that the combination of Triclosan and CPC produce a result which could not have been predicted based on the activity of Triclosan and CPC.

4. I declare that all statements made on my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeopardize the validity of the application and any patent issued thereon.

Dated: 2/19/99

  
Stephen Spainhour